SUMMARY OF SAFETY & EFFECTIVENESS

April 29, 2010

Glenveigh™

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

APPLICANT

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APR 30 2010

SUBMISSION CORRESPONDENT

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GLENVEIGH, LLC ESTABLISHMENT REGISTRATION NO.: We have submitted Form FDA 2891 through FDA FURLS and have received the owner/operator number 10029247 as a manufacturer.

1.2 DEVICE NAME & CLASSIFICATION

TRADE NAME:	Belfort-Dildy Obstetric Tamponade System (OTS)
COMMON NAME:	Obstetric-gynecologic specialized manual instrument Intrauterine tamponade balloon
DEVICE CLASSIFICATION:	Class II per 21 CFR §884.4530
PRODUCT CODE:	OQY

1.3 PREDICATE DEVICE INFORMATION

PREDICATE DEVICE:	K062438 & K013597 Cook Bakri Postpartum Tamponade Balloon K060289 Frontline Vaginal Tamponade Balloon K862480 Utah Medical BT Cath Uterine Tamponade Balloon

SUBSTANTIAL EQUIVALENCE:

The Belfort-Dildy Obstetric Tamponade System is substantially equivalent to other legally marketed post partum tamponade balloons with the same fundamental scientific technology, same intended use as the original, predicate devices, equivalent materials, same mechanisms and equivalent technological characteristics. Those device predicates are the Cook Bakri

Postpartum Tamponade Balloon K062438 and K013597 and Frontline Medical Tamponade Balloon K060289, and the Utah Medical BT-Cath Uterine Balloon Tamponade Catheter K862480.

All devices have the same method of operation to tamponade postpartum hemorrhage. Bench testing versus the predicate Bakri device has demonstrated that the Belfort-Dildy Obstetric Tamponade System is functionally equivalent to the Bakri predicate device and that any minor differences do not affect safety or effectiveness.

DESCRIPTION OF THE DEVICE:

The Belfort-Dildy Obstetric Tamponade System (OTS) is a disposable, multiple lumen catheter attached to an inflatable balloon system designed to provide tamponade for controlling hemorrhage from the uterus and vagina. The device consists of two inflatable balloons: The upper uterine balloon is inflated inside the uterus and the lower vaginal balloon is inflated inside the vagina. Inflation is accomplished with isotonic intravenous fluid such as normal saline or Ringers Lactate. The uterine balloon catheter has separate lumens to enable inflation/deflation, irrigation and drainage. The vaginal balloon catheter has a lumen to enable inflation/deflation. The uterine and vaginal balloons are permanently assembled and are not to be separated. The device may be retained in position for up to 24 hours in the post-operative mode of treatment. The Belfort-Dildy Obstetric Tamponade System (OTS) is supplied sterile in peel open pouches for one time use to a single patient.

INDICATIONS FOR USE:

The Belfort-Dildy Obstetric Tamponade System (OTS) is indicated for use in providing temporary control or reduction of postpartum uterine bleeding. Inflation of the Vaginal Balloon anchors the Uterine Balloon and provides vaginal tamponade if vaginal bleeding is present. The OTS should only be used in the setting of post-partum uterine bleeding when conservative management is warranted.

PERFORMANCE DATA:

The Belfort-Dildy Obstetric Tamponade System materials that come in direct contact with the patient have a long history of use in catheter manufacture and are demonstrated to be biocompatible through testing according to ISO 10993-1. Design verification performance test results demonstrate that the Belfort-Dildy Obstetric Tamponade System performs its intended use and is equivalent to the Bakri predicate device.

CONCLUSION:

Based on the performance testing and device attributes, it can be concluded that the Belfort-Dildy Obstetric Tamponade System is equivalent to the predicate devices with respect to intended use and technological characteristics.

DEPARTMENT OF HEALTH & HUMAN SERVICES

APR 30 2010

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Glenveigh Surgical, LLC
c/o Ms. Penny Northcutt, RAC, CQA
Regulatory Consultant for Glenveigh Surgical
REGSolutions, LLC
717 Lakeglen Drive
SUWANEE GA 30024

Re: K091958
Trade/Device Name: Belfort-Dildy Obstetric Tamponade System
Regulation Number: 21 CFR §884.4530
Regulation Name: Obstetric-gynecologic specialized manual instrument
Regulatory Class: II
Product Code: OQY
Dated: April 23, 2010
Received: April 26, 2010

Dear Ms. Northcutt:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

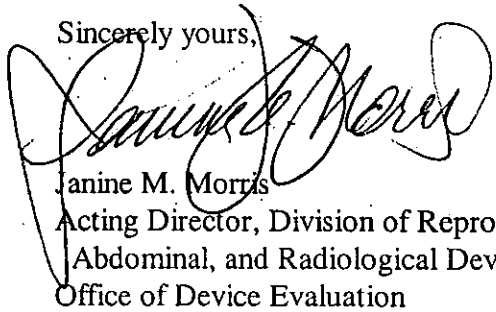
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related

adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091958

Device Name: BELFORT-DILDY OBSTETRIC TAMPONADE SYSTEM

Indications For Use:

The Belfort-Dildy Obstetric Tamponade System (OTS) is indicated for use in providing temporary control or reduction of postpartum uterine bleeding. Inflation of the Vaginal Balloon anchors the Uterine Balloon and provides vaginal tamponade if vaginal bleeding is present. The OTS should only be used in the setting of post-partum uterine bleeding when conservative management is warranted.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K091958